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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,413	05/04/2004	Yu-Jie Zhao	46863	3412

31561 7590 02/28/2006

JIANQ CHYUN INTELLECTUAL PROPERTY OFFICE
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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/709,413	ZHAO, YU-JIE	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 28 December 2005 has been entered. Claim 1 is currently amended. Claims 2 and 10-20 are canceled. Claims 1, 3-9 and 21 are pending in this application.

Withdrawn Rejections

Previous rejection of claims 1 and 3-9 under 35 USC 102(b) and 35 USC 103(a) have been withdrawn in light of applicant's arguments and amendments.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 2-9 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "the different" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being anticipated by Blackburn (US 2003/0190608) in view of Fodstad et al. (US 2005/0130234, priority date 18 June 1999).

Blackburn teaches a method of fabricating a cell detection chip, comprising: selecting a plurality of probe molecules, wherein an affinity exists between each of the probe molecules and one of corresponding antigens on a cell membrane (different capture probes are specific for analyte, par. 150; analyte are antigens on cell membranes, par. 103); modifying the plurality of probe molecules to facility an immobilization of the probe molecules onto a matrix (par. 162); and spotting the probe molecules respectively onto respective positions of the matrix (par. 152-153), but fails to teach the selection of the plurality of probe molecules based on different corresponding specific molecules on the cell membrane between normal cells and pathologically changed cells.

Fodstad et al. teach that a plurality of probe molecules may be selected based on different corresponding specific molecules on the cell membrane between normal cells and pathologically changed cells (target antibodies detect four different antigenic determinants of a disease expressed on membrane of a target cell, par. 17) to identify various types of one disease (different types of breast cancer are detected by using different determinants for antigens expressed on the surface membrane of the tumor cells, par. 29), in order to identify and characterize target pathological cells.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the selecting step of the method of Blackburn, selection of a plurality of probe molecules based on specific molecules on a cell membrane between normal cells and pathologically changed cells as taught by Fodstad et al., in order to study abnormal cells such as malignant and benign neoplastic cells, and abnormal cells found in various infectious, reactive, autoimmune, inflammatory and proliferative disorders.

Blackburn teaches that identification is based on test results of major indication (signal from labeled probes are detected which provides indication of presence of antigens, par. 266).

2. Claims 1, 4-6, 9 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Okamoto et al. (US 2003/0059817) in view of Kapur et al. (US 6,548,263), further in view of Fodstad et al. (US 2005/0130234, priority 18 June 1999).

With respect to claims 1 and 6, Okamoto et al. teach a method of fabricating a cell detection chip, comprising: designing a plurality of probe molecules, wherein an affinity exists between each of the probe molecules and one of corresponding specific molecules (par. 0056); synthesizing a plurality of probe molecules (par. 0046, 0056); spotting the probe molecules respectively on a matrix (par. 0056); and incubating the matrix to keep the matrix under a wet environment (support stood in a humid chamber for 30 minutes, par. 0056). Okamoto et al. fail to teach specific molecules being on a cell membrane and selection of the plurality of probe molecules based on different corresponding specific molecules on the cell membrane between normal cells and pathologically changed cells.

Kapur et al. teach a spotted array comprising probe molecules (col. 13, lines 50-67; col. 14, lines 53-55) wherein the corresponding specific molecule (analyte) is an antigen on a cell membrane (col. 15, lines 62-67), in order to provide a high throughput specific cell-type binding microarray. Kapur et al. fail to teach selection of the plurality of probe molecules based on different corresponding specific molecules on the cell membrane between normal cells and pathologically changed cells.

Fodstad et al. teach that a plurality of probe molecules may be selected based on different corresponding specific molecules on the cell membrane between normal cells and pathologically

changed cells (target antibodies detect four different antigenic determinants of a disease expressed on membrane of a target cell, par. 17) to identify various types of one disease (different types of breast cancer are detected by using different determinants for antigens expressed on the surface membrane of the tumor cells, par. 29), in order to identify and characterize target pathological cells.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Okamoto et al., specific molecules on the surface of cell membranes as taught by Kapur et al., in order to provide high biological content screening for drug candidates by analysis of drug-cell interactions when a small number of cells and large volumes of compounds required for testing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the selection step of the method of Okamoto et al. in view of Kapur et al., selection of a plurality of probe molecules based on specific molecules on a cell membrane between normal cells and pathologically changed cells as taught by Fodstad et al., in order to study abnormal cells such as malignant and benign neoplastic cells, and abnormal cells found in various infectious, reactive, autoimmune, inflammatory and proliferative disorders.

Regarding claims 4 and 5, Okamoto et al. teach designing probe molecules comprising a plurality of location indication probes (par. 0118) and the step of synthesizing the probe molecules, further comprising the step of dissolving probe molecules in a solvent to form a solution of the probe molecules (probe molecules are mixed in a solution, par. 0056).

With respect to claim 9, Okamoto et al. teach a spot diameter between 20 and 100 μm (par. 0033), which encompasses the recited range of a spot radius between 50 and 500 μm.

Regarding claim 21, Okamoto et al. teach identification based on test results of major indication (fluorescent signal provides optical detection of presence of a target sample which is a test result of major indication, par. 68).

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al. (US 2003/0059817) in view of Kapur et al. (US 6,548,263), as applied to claim 1, and further in view of Chen et al. (US 6,594,432).

Okamoto et al. in view of Kapur et al., as applied to claim 1, teach a method of fabricating a cell detection chip, but fail to teach the step of designing probe molecules further comprising designing a plurality of quality control probes.

Chen et al. teach using a plurality of quality control probes (col. 7, lines 10-22), in order to inspect microarrays after their formation.

Therefore it would have been obvious to on having ordinary skill in the art at the time the invention was made to include in the designing step of the method of Okamoto et al. in view of Kapur et al., designing a plurality of quality control probes as taught by Chen et al., in order to determine if probes have been deposited.

4. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto et al. (US 2003/0059817) in view of Kapur et al. (US 6,548,263) further in view of Oprandy (US 5,200,312).

Okamoto et al. in view of Kapur et al., as applied to claims 1 and 6, teach a method of fabricating a cell detection chip and a step of cleaning after incubation (par. 0116), but fail to teach a step of drying after an incubation step and before cleaning.

Oprandy teaches a step of drying (col. 4, lines 11-19), in order to store an antibody bound membrane for later use.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of fabricating a chip after the step of incubation and the step of cleaning of Okamoto et al. in view of Kapur et al., a step of drying as taught by Oprandy, in order to ensure the probe has completely bound to the matrix.

With respect to claim 8, Okamoto et al. teach after the step of cleaning, steps of: blocking portions of a surface of the matrix not spotted with probes, wherein a blocking solution is used (immersed in bovine serum albumin to proceed blocking reaction, par. 0116); and further cleaning the matrix (matrix is washed after hybridization reaction, par. 0118).

Response to Arguments

5. Applicant's arguments, see pages 5-10, filed 28 December 2005, with respect to the rejection(s) of claim(s) 1, 3-9 and 21 under 35 USC 102(e) and 35 USC 103(a) have been fully considered. The previous rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's addition of the new limitation requiring a selection of a plurality of probe molecules based on different corresponding specific molecules on a cell membrane between normal cells and pathologically changed cells to identify various types of one disease.

Conclusion

No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu

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02/17/06